REMARKS

Claims 1, 2 and 10-18 are presently pending in this application. Claims 3-9 have been previously canceled. Claims 19 and 20 have been cancelled without prejudice to filing one or more divisional applications directed to the non-elected subject matter. Claim 1 has been amended to deleted compounds III through and including IX without prejudice to filing one or more divisional applications to the non-elected subject matter.

Rejection under 35 U.S.C. §112, First Paragraph

Claims 1, 2 and 10-18 have been rejected under 35 U.S.C. §112, first paragraph, as purportedly failing to comply with the enablement requirement. Specifically, the Office Action alleges that "the recitation of 'prevention of demyelination' in the instant claims directs the claims to methods of preventing a pathological condition. However, the specification fails to properly enable such methods." (Office Action at page 3).

While Applicants respectfully disagree with and traverse this rejection, claims 1, 17 and 18 have been amended to delete "preventing" from these claims, without prejudice. Accordingly, since claims 2 and 10-16 ultimately depend from claim 1, claims 2 and 10-16 also no longer recite "preventing" demyelination. For this reason, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. §102

Claims 1, 2 and 10-18 have been rejected under 35 U.S.C. §102 as being anticipated by van Heek *et al.* (Diabetes (2001) 50:1330-1335). Applicants respectfully traverse this rejection for the reasons below, and request reconsideration and withdrawal of this rejection.

The claimed invention is directed to a method of treating demyelination comprising administering at least one of the recited sterol absorption inhibitor (or a pharmaceutically acceptable salt or solvate thereof). Heek *et al.* is directed to administering ezetimibe to rodents to eliminate the accumulation of cholesteryl ester and free cholesterol in the liver that is induced by various dietary conditions (see Heek *et al.* abstract). Since Heek

et al. is not directed to treating demyelination, the Examiner relied upon the doctrine of inherency to assert that Heek *et al.* inherently anticipates the claimed invention.

Heek *et al.* does not expressly teach the claimed method of treating demyelination. Presently pending claim 1 is directed to "a method of treating demyelination in a subject, comprising the step of administering to a subject in need of such treatment ...." The proper interpretation of this language requires that the claims be read to include the limitations that the claimed method be performed *for the purpose of* treating demyelination, as dictated by the Federal Circuit in their *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329 (Fed. Cir. 2003) and *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001) decisions.

In *Jansen*, the claim at issue was directed to:

> 1. A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is cause by either folic acid deficiency or by vitamin B_{12} deficiency which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof comprising at least about 0.5 mg of vitamin B_{12} and at least about 0.5 mg. of folic acid.

Jansen at 1330. The Federal Circuit held that the language "to a human in need thereof" appearing in the body of the claim in combination with the preamble language "[a] method of treating or preventing macrocytic-megaloblastic anemia" required the claim to be interpreted so as to include the limitation that the claimed composition be administered <u>for the purpose of</u> treating or preventing macrocytic-megaloblastic anemia. *Id.* at 1334. The prior art cited against the *Jansen* patent disclosed the administration of buspirone to a patient suffering from sleep apnea for the purpose of treating anxity caused by the underlying sleep apnea condition. *Id.* at 1334. Thus, the patient population of the method claimed in *Jansen* – persons suffering from sleep apnea – encompassd the population disclosed in the prior art – those suffering from sleep apnea-induced anxiety. The only distinction between the populations is the *purpose* for which the members of the population were taking the buspirone. As discussed in greater detail below, the claimed invention and the use disclosed in Heek *et al.* serve diverging purposes; therefore, Heek *et al.* does not teach or suggest a method of treating demyelination.

In Rapoport, on which the Jansen court relied, the claim at issue was directed to:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment...

Rapoport at 1056. In a subsequent interference proceeding, the phrase "treatment of sleep apneas" was treated as a claim limitation because, without doing so, the phrase "to a patient in need of such treatment" would not have the proper antecedent basis. Id. at 1059.

The correct construction of Applicants' claims is that the claimed method is to be used for the purpose or intent, to treat demyelination. Claim 1 of the present application is analogous to the claims at issue in *Jansen* and *Rapoport* since the purpose of the claimed method appears in the preamble and serves as the antecedent basis for language appearing within the claim body.

Nor does Heek *et al.* implicitly or inherently teach a method of treating demyelination because treating demyelination is not a necessary feature of treating the accumulation of cholesteryl ester and free cholesterol in the liver. "The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under [Sections 102 or 103]." MPEP §2112. However, if an examiner asserts that a feature is inherently disclosed by a reference, that inherent feature must be a necessary feature in a prior-art embodiment. MPEP § 2112, *citing Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004); see also *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed.Cir. 2002), *quoting Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed.Cir. 1991), *also quoting Trintec Indus., Inc. v. Top U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed.Cir. 2002).

In *Astrazeneca v. Mutual Pharmaceutical Co.*, the Court found that a reference, which disclosed using PEG 400, did not disclose using a solubilizer, and therefore did not anticipate the claims of the subject patent, even though PEG 400 was known to be capable of functioning as a solubilizer. 278 F.Supp.2d 491, 512 (E.D. Pa 2003). The Court reasoned that merely because PEG 400 was capable of functioning as a solubilizer does not

mean that the reference necessarily used PEG 400 as a solubilizer. *Id.* Therefore, the reference did not inherently anticipate the subject claims.

Likewise, *Ex parte Novitski*, 26 U.S.P.Q.2d 1389 (B.P.A. 1993) follows this rule that a reference can only inherently disclose a claimed feature if that feature is necessary. In *Novitski*, the claimed invention was "a method for protecting a plant from plant pathogenic nematodes which comprises the step of inoculating said plant with a nematode-inhibiting strain of *P. cepacia* which strain colonizes said plant." *Id.* at 1389. Dart, the reference relied upon to reject the claims in Novitski's application, did not expressly disclose protecting a plant from pathogenic nematode, but did disclose "inoculating a plant with *Pseudomonas cepacia* type Wisconsin 526." *Id.* at 1390. This step necessarily constituted a method of protecting a plant from a plant pathogenic nematode because the purpose of Dart was to protect plants from parasitic infection. *Id.* Therefore, the Board held that Dart inherently anticipated the subject claims.

In contrast, since Heek *et al.* does not disclose a method intended to treat demyelination, it does not inherently disclose the claimed invention. In point of fact, Heek *et al.* has nothing to do with treating demyelination. Neurons are not even mentioned once in Heek *et al.* Therefore, treating demyelination is not a necessary feature of Heek *et al.*'s use of ezetimibe. Since this feature of ezetimibe is not necessary, Heek *et al.* cannot be relied upon as inherently teaching treating demyelination by administering ezetimibe, let alone any of the other claimed formulas.

To support a rejection under Section 102, an examiner must show that each and every element recited in the claimed invention is taught by a single reference. MPEP § 2131. Since Heek *et al.* does not inherently teach administering ezetimibe to treat demyelination, it fails to teach each and every element recited in the claims. For this reason, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Conclusion

In view of forgoing amendments and remarks, Applicants respectfully request reconsideration of all pending claims, and that the rejections asserted in the July 27, 2007 Office Action be withdrawn because all pending claims are patentable over the prior art and in condition for allowance. Accordingly, a Notice of Allowance is respectfully requested.

Respectfully submitted,

The Webb Law Firm

Date: October 26, 2007 By:

Thomas C. Wolski
Registration No. 55,739
The Webb Law Firm
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219
Phone: (412) 471-8815
Fax: (412) 471-4094
E-mail webb@webblaw.com